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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,622	02/07/2002	Lieping Chen	07039-331001	3225
26191	7590	07/07/2006	EXAMINER	
FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/072,622	Applicant(s) CHEN ET AL.	
	Examiner ILIA OUSPENSKI	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,3-8 and 12-26 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/05/2006 has been entered.

2. Applicant's amendment/remarks, filed 05/05/2006, are acknowledged.

Claim 27 has been cancelled.

Claims 2 and 9 – 11 have been cancelled previously.

Claims 1, 3, and 5 have been amended.

Claims 1, 3 – 8, and 12 – 26 are pending.

Claims 8 and 12 – 23 have been withdrawn from consideration by the Examiner as being drawn to nonelected inventions (see Office Action mailed 05/03/2005).

Claims 1, 3 – 7, and 24 – 26 are under consideration in the instant application.

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3. This Office Action will be in response to applicant's amendment and arguments, filed 05/05/2006.

The rejections of record can be found in the previous Office Action, mailed 12/06/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

It is noted that New Grounds of Rejection are set forth herein.

4. The rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

5. Claims 1, 3 – 7, and 24 – 26 stand rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation of "B7-H2" because its identity is unclear.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the amendment to claim 1 to recite "human" B7-H2 makes the claims definite.

This is not found persuasive, because, as noted previously, the name "B7-H2" is also used to designate a different B7-related protein (e.g. Coyle et al., US Patent No. 6,630,575; see e.g. Summary of Invention at columns 3 – 4). Therefore, one of ordinary

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skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

6. Claims 1, 3 – 7, and 24 – 26 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to the specification at page 5 for support for the newly added limitation "a fragment of art least 15 amino acids of the extracellular domain." However, the specification does not appear to provide an adequate written description of this limitation.

It is acknowledged that the specification at page 5, lines 18 – 22 discloses fragments of various lengths of an "ICOS polypeptide," however, this is not seen as sufficient support under 35 USC 112 for the specific recitations of "a fragment of at least 15 amino acids" or "a fragment [...] of the extracellular domain."

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

7. Claim 26 stands rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

The recitation of a fusion polypeptide comprising ICOS and an “immunoglobulin Fc fragment” sequence” represents a departure from the specification and the claims as originally filed.

Applicant’s arguments have been fully considered but have not been found convincing.

Applicant points to the specification at page 11, lines 24 – 31, and page 18, lines 15 – 18, for support of the above recitation. It is acknowledged that the specification discloses that that an ICOSIg polypeptide can be produced by linking sequences of ICOS and “Ig,” and or ICOS and “the CH2-CH3 portion of human IgG1;” however, neither passage alone nor their combination provide sufficient support under 35 USC 112, first paragraph, for the generic recitation of “immunoglobulin Fc fragment.”

Therefore, the rejection of record is maintained for the reasons of record. The rejection of record is incorporated by reference herein, as if reiterated in full.

8. Claims 1, 3, 5, 7, and 24 – 26 stand rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a variant of an amino acid sequence consisting of an extracellular domain of wild-type ICOS, does not reasonably provide enablement for a variant of a wild type ICOS amino acid sequence consisting of a fragment of at least 15 amino acids of the extracellular domain.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Given the absence of additional rebuttal to the outstanding rejection of record in applicant's amendment, the rejections are maintained for the reasons of record.

Additionally, it is noted that the specification discloses that the ligand binding regions of ICOS are distributed between stretches of amino acids 49 – 52, 64 – 68, 75 – 78, and 114 – 119 (e.g. page 5, first complete paragraph). Therefore, a skilled artisan would conclude that at least the region of amino acids 49 – 119 is required for ligand binding, and thus a skilled artisan would conclude that a fragment not comprising this region is not expected to possess the claimed properties.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

9. Conclusion: no claim is allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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June 30, 2006

Phillip Gambel
PHILLIP GAMBEL, PH.D. .S.D.
PRIMARY EXAMINER
TZ

1600
7/2/06